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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,606	12/11/2003	Bei Chen	ABGENIX.058A	9342

20995 7590 04/03/2006

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EXAMINER	
KIM, YUNSOO	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 04/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/734,606	CHEN ET AL.	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/17/06*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) *10-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 25-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed 1/17/06 has been entered.

Claims 1-4, 8, 9, 25, 29-34, 38 and 39 have been amended.

Claims 10-24 remain withdrawn.

Claims 40-48 have been added.

Claims 1-9 and 25-48 are under consideration.

2. In view of Applicants' amendment to the claims, the rejection under 35 U.S.C. 102 and 103 (sections 6-11) set forth in the office action mailed 9/14/05 have been withdrawn.

3. The following new ground of rejection is necessitated by Applicants' amendments and addition of new claims on 1/17/06.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-3, 5, 6, 8, 9, 25-27, 29, 30-40, 42, 43, 45, 46 and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by US2003/0138417 A1 as is evidenced by the SYNAGIS ® product information sheet.

The '417 publication teaches a lyophilized human monoclonal IgG1 formulation in 20-60mM of Histidine (e.g.47mM histidine), 3mM glycine and 5.6% mannitol (e.g. additional excipients, [0004]).

The '417 publication further teaches the formulation is packaged and supplied with sterile water to give the concentration of 50mg-100mg/ml as further evidenced in the SYNAGIS ® product information sheet ([0004]).

In addition, the '417 publication teaches a stable liquid formulation comprising 50mg/ml IgG2 (e.g. HuEP5C7, human monoclonal antibody to selectin [0044]) in 50mM of Histidine, 125 mM NaCl (Example 11, [0107-0109], abstract) and arginine ([0052]).

The claims 25-27, 29, 30, 43 and 45 drawn to "kit" are included in this rejection as the '417 publication teaches supplying sterile water (e.g. solution) with the lyophilized product. Thus, prior art teachings anticipate the claimed invention.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 4, 7 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US2003/0138417 in view of U.S. Pat. No. 5,580,856.

The '417 publication has been discussed, supra.

The '417 publication does not teach IgG2 antibody or use of arginine in a lyophilized (freeze-dried) formulation.

However, the '856 patent teaches a process of drying (i.e. freeze drying or spray draying) is often employed to stabilize proteins in a lyophilized formulation for long-term storage (abstract, col. 1, lines 5-14).

Therefore, one of the ordinary skill in the art would have been motivated to combine drying process as taught the '856 patent to stabilize proteins in a lyophilized formulation for long-term storage.

From the teachings of references, it would have been obvious to one of ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time of invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

8. Claims 1, 41 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over US2003/0138417 and U.S. Pat. No. 5,580,856 in view of U.S. Pat. No. 4,849,352.

The '417 publication and the '856 patent have been discussed, supra.

The '417 publication and the '856 patent do not teach immunospecific antibody fragments (e.g. $F(ab')_2$).

However, the '352 patent teaches a pharmaceutical composition comprising a polyclonal $F(ab')_2$ binds to any antigen, pepsin digested followed by ammonium sulfate precipitation (col. 3, lines 22-41, col. 2, lines 51-65). The '352 patent further teaches that the antibody fragments are quickly distributed in the body, filtered and excreted by the kidney. Toxin neutralization by antibody fragments and volume circulating are greater than IgG (col. 1-2 overlapping paragraph).

Therefore, one of the ordinary skill in the art would have been motivated to combine teachings of antibody fragment taught by the '352 patent in the teachings of the '417 publication and the '856 patent to produce more readily utilizable antibody. The '352 patent teaches intact IgG is too large to excreted by kidney functions (col. 2, lines 22-50).

From the combined teachings of references, one of ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary skill in the art at the time the invention was made, as evidenced by references, especially in the absence of evidence to the contrary.

9. No claims are allowable.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yunsoo Kim
Patent Examiner
Technology Center 1600
March 16, 2006

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